any description of sufficient, relevant, identifying characteristics [*i.e.* complete or partial structure, other physical or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics] so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." *Id.* at 2163 (II)(A)(3) citing *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000)."

In conjunction with the remarks and evidence already of record, applicant submits that the Specification adequately describes the elements of claims 21-27 by structure, functional characteristics, and combinations thereof. Claim 21 recites, in part,

> "...a nucleotide sequence of *Streptococcus suis* origin wherein the nucleotide sequence comprises a contiguous sequence which hybridizes to the full length of nucleotides 89-263 of the nucleotide sequence of SEQ ID NO:37... and wherein the complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*."

Thus, the nucleotide sequence of claim 21 is a contiguous sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37. Additionally, the complement of nucleotide sequence of claim 21 encodes for a portion a fibronectin-/fibrinogen-binding protein of *S. suis.*

In the Final Office Action, it was alleged that "there is no disclosure of a nucleic acid molecule that hybridizes to SEQ ID NO:37 and the complement of the hybridizing nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein..." Final Office Action, page 5. Additionally, it was alleged that "the specification fails to provide guidance on the structure of the claimed nucleic acid molecule." *Id.* at 6.

Applicant respectfully disagrees. In the response submitted September 24, 2008, applicant referenced paragraphs **[0105]-[0106]** which describe the production and isolation of a 5kb fragment and pFBPS7-46, both of *Streptococcus suis* origin. Indeed, these arguments were acknowledged by the Examiner. Paragraph **[0105]** states that SEQ ID NO:37 was used as a probe to identify a chromosomal fragment of *S. suis* serotype 2 containing flanking fbps sequences. *See* Paragraph **[0105]**. Because the chromosomal fragment was identified using the SEQ ID NO:37 probe, this described nucleic acid fragment necessarily includes a complementary sequence that hybridizes to SEQ ID NO:37. Thus, at the very least, the Specification describes a nucleic acid sequence that hybridizes to and is complementary to SEQ ID NO:37, in accordance

with applicant's claims.[1]

Applicant further submits that the complement of the described nucleic acid sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37 under the recited conditions would have a complement that necessarily includes a nucleotide sequence that encodes for a portion of a fibronectin-/fibrinogen-binding protein of *S. suis*. Because the described nucleotide sequence, or fragment including the claimed nucleotide sequence, is complementary to SEQ ID NO:37 [apparent by its hybridization to SEQ ID NO:37], a complement of a claimed nucleic acid sequence would necessarily include nucleotides 89-263 of SEQ ID NO:37. Illustrated and described in previous responses, nucleotides 89-263 of SEQ ID NO:37 encode for a portion of a fibronectin-/fibrinogen-binding protein of *S. suis*.[2] Accordingly, the claimed nucleotide sequence's complement would necessarily include a nucleotide sequence that encodes for a portion of a fibronectin-/fibrinogen-binding protein of *S. suis*.

Furthermore, the Examiner's statements support the disclosure of the isolated and claimed nucleic acid sequence. The Final Office Action states "because hybridization under highly stringent conditions requires a high degree of structural complementarity, nucleic acids that hybridize to SEQ ID NO:37 must share many nucleotides in common with SEQ ID NO:37." Final Office Action at 5. Thus, because of the "highly stringent conditions" as presently claimed, the Specification's described 5kb fragment and pFBPS7-46 would necessarily include a contiguous sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37, as presently claimed. Accordingly, the Specification describes the claimed nucleic acid structurally, functionally, and by relevant characteristics.

In the Final Office Action, it was additionally alleged that the issue is:

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[1] In the event the Specification's described 5kb fragment and pFBPS7-46 was not a complement to SEQ ID NO:37, which applicant disputes, no nucleic acid fragments would likely have hybridized to the SEQ ID NO:37 probe. However, this is not the case, as can be seen in paragraphs **[0105]-[0106]** of the Specification.

[2] The Blast and Alignment provided in the response submitted September 24, 2008 shows that nucleotides 89-263 of SEQ ID NO:37 encode for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis*. *See, e.g.,* Response submitted September 24, 2008, page 7. Furthermore, as described in the previous response, in paragraph **[0102]** of the Specification references Genbank accession no. AF438158. The nucleotide sequence of Accession no. AF438158 encodes a fibronectin-/fibrinogen-binding protein of *S. sui*, as shown by the Blast and

> "that the specification does not indicate that any nucleic acids that hybridize to SEQ ID NO:37 under the recited conditions and complement of the nucleotide sequence encodes for a portion of a fibronectin-/fibrinogen-binding protein of *Streptococcus suis." Id.* at 4.

The Examiner further alleges that the scope of the claims "includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted." *Id.* at 6.

Applicant respectfully notes that the claims are not directed to "any" nucleic acid sequence that hybridizes to or complements SEQ ID NO:37, but rather to those specific nucleic acid sequences that hybridize to or complement nucleotides 89-263 of SEQ ID NO:37 and whose complement encodes for a portion of a fibronectin-/fibrinogen-binding protein of *S. suis*. Additionally, the Examiner's statements with regard to the claimed "highly stringent conditions requiring a high degree of structural complementarity" at the very least suggest that the claims are not directed to "any" nucleic acid sequence that hybridizes to or complements SEQ ID NO:37.

Applicant submits that the enclosed sequences of the *fbps* gene (Exhibit A), the predicted FBPS protein submitted to GenBank as AF438159 [referenced in **[0102]** of the Specification] (Exhibit B), and a homology search on the sequence of the FBPS protein (Exhibit C) suggest that any potential nucleic acid sequences that hybridize under the recited conditions would encode for a fibronectin-/fibrinogen-binding protein of *S. suis*. Indeed, the homology search in Exhibit C suggests that proteins with as low as fifty percent (50%) homology to the FBPS proteins of *S. suis* are FBPS proteins. Furthermore, these homologous proteins are not only from *S. suis,* but from other strains as well.

It was further alleged that "contrary to applicant's assertions, possession of SEQ ID NO:37 does not equate to possession of the claimed nucleic acid sequence." *Id.* at 4. In response, applicant does not assert that possession of SEQ ID NO:37 equates to possession of the claimed nucleic acid sequence. Rather, applicant submits that in view of the evidence of record and the remarks presented herein, the Specification adequately describes the claimed nucleic acid sequence and that the complement of the claimed nucleic acid sequence encodes for a portion of

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Alignment of Exhibits A-C submitted herewith.

a fibronectin-/fibrinogen-binding protein of *S. suis*.

In light of the above, applicant asserts that the Specification provides more than adequate written description for the present claims, and thus, respectfully requests withdrawal of the written description rejection under 35 U.S.C. § 112, first paragraph.

Claims 21-27 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly including new matter. Applicant respectfully traverses the rejection.

It appears to the applicant that the Examiner failed to specifically respond to all the comments presented in the response submitted September 24, 2008. Accordingly, applicant has re-presented the analysis herein.

The Specification, in at least paragraph **[0082],** expressly describes the hybridization conditions as presently claimed.

Additionally, as discussed in the paragraphs responding to the "written description" issues, the Specification in at least paragraphs **[0105]-[0106]** provides a more than adequate disclosure for an isolated or recombinant nucleotide sequence that hybridizes to full length of nucleotides 89-263 SEQ ID NO:37. Applicant respectfully asserts that, at the very least, the Specification inherently discloses "a nucleotide sequence comprising a contiguous sequence that hybridizes to the full length of nucleotides 89-263 of SEQ ID NO:37.

Applicant respectfully notes that "[an] application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *See,* MPEP § 2163.07 (a), citing *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). The MPEP further states that "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it." *Id.* As is clear from the remarks presented herein, the inherent properties of the claimed nucleotide fragment are "necessarily present" in the disclosed pFBPS7-46 and 5kb fragment, and not a mere possibility.

As discussed in paragraphs responding to the "written description" issues, the Specification, at the very least, inherently describes an isolated or recombinant nucleotide sequence that hybridizes to full length of nucleotides 89-263 SEQ ID NO:37. Applicant reasserts

that the evidence of record demonstrates that pFBPS7-46 and the 5kb fragment necessarily include a recombinant or isolated nucleotide sequence that hybridizes fully to sequences 89-263 of SEQ ID NO:37 and that such an inclusion is not a mere possibility.

Additionally, as previously discussed, the Specification more than adequately discloses that the complement of the disclosed nucleotide sequence encodes for a portion of a fibronectin/fibrinogen binding protein of *S. suis*.

Applicant submits that in view of the foregoing, the Specification more than adequately describes the isolated or recombinant nucleotide sequence as presently claimed. Applicant additionally submits that such disclosure would be readily apparent to one of ordinary skill, as the disclosure, in part, is based on the common principles of nucleic acid hybridization. Accordingly, applicant respectfully requests withdrawal of the 35 U.S.C § 112, first paragraph, new matter rejection.

Claim 28/29

Claims 28-29 stand withdrawn from consideration, as the Examiner alleges that claim 28-29 are directed to an independent invention. Specifically, the Examiner alleges that because the elected claims were drawn to nucleotide sequences capable of hybridizing to SEQ ID NO:37, claims 28 and 29 are directed to a non-elected invention.

With regard to claim 29, applicant respectfully disagrees. Claim 29 recites, in part, an isolated or recombinant double stranded nucleic acid molecule comprising... "a means for hybridizing to the nucleotide sequence of SEQ ID NO:37." Accordingly, claim 29 is not directed to a sequence comprising SEQ ID NO:37. Rather, claim 29 is directed to a nucleotide sequence having a means for hybridizing to SEQ ID NO:37.

As remarked in the Office Action submitted April 2, 2008, claim 29 is presented in a means-plus-function format as permitted by 35 U.S.C. § 112, paragraph six. *See* applicant's response submitted April 2, 2208, pages 9-11. Because the "means" for hybridizing to the nucleotide sequence of SEQ ID NO:37 is, in essence, a nucleotide sequence, claim 29 is directed to applicant's previously elected subject matter.

Applicant submits that in view of the arguments and evidence presented herein and the evidence already of record, claim 29 is more than adequately described pursuant to 35 U.S.C. §

112, first paragraph. Accordingly, applicant respectfully requests consideration and allowance of claim 29.

CONCLUSION

In light of the above remarks, the application is believed to be in condition for allowance. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicant's attorney at the address or telephone number given herein.

Respectfully submitted,

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Telephone: 801-532-1922

Enclosures: Supplemental Information Disclosure Statement
Exhibits A, B, and C

Date: March 23, 2009
TEN/ten
Document in ProLaw

EXHIBIT A

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Entry history

UniProtKB/TrEMBL entry Q8RP86

[Entry info] [Name and origin] [References] [Comments] [Cross-references] [Keywords] [Features] [Sequence] [Tools]

Note: most headings are clickable, even if they don't appear as links. They link to the user manual or other documents.

Entry information

Entry name	**Q8RP86_STRSU**
Primary accession number	**Q8RP86**
Secondary accession numbers	None
Integrated into TrEMBL on	June 1, 2002
Sequence was last modified on	June 1, 2002 (Sequence version 1)
Annotations were last modified on	July 22, 2008 (Entry version 13)

Name and origin of the protein

Protein name	**Fibronectin/fibrinogen binding protein**
Synonyms	None
Gene name	**Name: fbps**
From	Streptococcus suis [TaxID: 1307]
Taxonomy	Bacteria; Firmicutes; Lactobacillales; Streptococcaceae; Streptococcus.
Protein existence	4: Predicted;

References

[1] NUCLEOTIDE SEQUENCE.
DOI=10.1128/IAI.70.3.1319-1325.2002; PubMed=11854216 [NCBI, ExPASy, EBI, Israel, .
de Greeff A., Buys H., Verhaar R., Dijkstra J., van Alphen L., Smith H.E.;
"Contribution of fibronectin-binding protein to pathogenesis of Streptococcus suis serotype
Infect. Immun. 70:1319-1325(2002).

Comments

Cross-references

Sequence databases

EMBL	AF438158; AAL85276.1; -; Genomic_DNA.	[EMBL / GenBank / DDBJ] [CoDingSequence]

3D structure databases

ModBase Q8RP86.

Family and domain databases

InterPro	IPR008532; DUF814. IPR008616; Fibro_bd_N. Graphical view of domain structure.
Pfam	PF05670; DUF814; 1. PF05833; FbpA; 1. Pfam graphical view of domain structure.

Other

UniRef View cluster of proteins with at least 50% / 90% / 100% identity.

Keywords

None

Features

None

Sequence information

Length: **552 AA** Molecular weight: **63310 Da** CRC64: **054A464BB669F165** [This is a checksum of sequence]

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       130        140        150        160        170        180
EIMGKHSNII LVDKSEQKII EAIKHVGFSQ NSYRTILPGS TYIRPPETHS LNPYTVSDEK

       190        200        210        220        230        240
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BLAST submission on ExPASy/SIB or at NCBI (USA)

Sequence analysis tools: ProtParam, ProtScale, Compute pI/Mw, PeptideMass, PeptideCutter, Dotlet (Java)

ScanProsite, MotifScan

Submit a homology modeling request to SWISS-MODEL

NPSA Sequence analysis tools

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EXHIBIT B

Entry Information

Entry from: EMBL (Coding Sequences)

Entry Options

Launch analysis tool: NCBI BLASTN Launch

Link to related information: Link

Save entry: Save

View: Printer Friendly

General Description Features Sequence

General Information

Entry Name	EMBLCDS:AAL85276
Parent Accession	AF438158.1
Molecule Type	linear genomic DNA
Sequence Length	1659
Entry Division	PRO (*Prokaryotes*)
Entry Data Class	STD (*Standard*)
Internal Sequence Version	AAL85276.1

Description

Description	Streptococcus suis fibronectin/fibrinogen binding protein
Organism	Streptococcus suis
Organism Classification	Bacteria; Firmicutes; Lactobacillales; Streptococcaceae; Streptococcus.
NCBI TaxID	1307

Related entries

Related by			
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	Exon	2	About
	Inference	N/A	About
	NCBI TaxId	1397	About
	Sequence Identity	1	About

Features

Key	Location	Qualifier	Va
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Sequence

Characteristics: **Length:** 1659 BP, **A Count:**491, **C Count:**397, **G Count:**396, **T Count:**375, **Others Count:**0 **CRC:**1123929667

Display Format: (•) FASTA ( ) GCG ( ) EMBL ( ) GenBank ( ) Pretty

Sequence

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General Description Features Sequence

EXHIBIT C

1 result for **Q8RP86 AND identity:0.5** in **UniRef**

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